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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/931,721	09/16/1997	BARBARA PAPADOPOULOU	1038-729MIS:	4535

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06/04/2003

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EXAMINER

GUCKER, STEPHEN

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/931,721

Applicant(s)

Papadopoulos et al.

Examiner

Stephen Jucker

Group Art Unit

1647

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.

- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.

- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 3/19/03
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 3-7, 9-10, & 21 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 3-7, 9-10, & 21 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Art Unit: 1647

Response to Amendment

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1647.
2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/19/03 has been entered.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.
5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 3-7, 9-10 and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of US 6,331,304 B1 in view of Modabber. Although the conflicting claims are not identical, they are not patentably distinct from each other because a macrophage infesting parasite is obvious over the immunogenic composition comprising an attenuated macrophage infesting parasite because Modabber teaches that live, unattenuated macrophage infesting parasites have already been used as immunogenic compositions (page S49 and page S52) for the purpose of 'leishmanization'. The patented claims do not teach the suitability of the unattenuated organism for vaccination. Modabber does teach the suitability of the unattenuated organism for simple vaccinations ('leishmanization'). One of ordinary skill in the art at the time the invention was made would have the desire and motivation to make a macrophage infecting parasite as claimed because such a parasite would be a pathogen with reduced pathogenicity due to the transfection of GM-CSF into the infecting organism. Immunogenic compositions comprising pathogens with reduced pathogenicity are routinely made and used in the art as simple vaccines, particularly in third world countries as taught by Modabber, specifically live unattenuated *Leishmania* strains used as vaccines against leishmaniasis.
7. Claims 1, 3-7, 9-10 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

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one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant claims recite the term "gene" which is no longer being read by the PTO as just a nucleic acid encoding a protein, because of the great strides made in genetic engineering and the decoding of an ever growing number of total genomes from various species, including the human genome.. The term "gene" is now being given a broader definition that comprises all of the various non-coding regions and specific critical sites (initiation, transcription, alternate splicing, etc.) that comprise genetic material found in the chromosome. The instant specification is silent as to the nucleotide composition and ordering of the non-coding regions of the GM-CSF gene, and therefore cannot adequately describe it. This is in contrast to a description of a nucleic acid encoding GM-CSF, which has adequate description and support in the specification and the prior art that the specification refers to. Amending the claim to recite nucleic acid encoding granulocyte macrophage colony stimulating factor (GM-CSF) in lieu of a GM-CSF gene would obviate the grounds of this rejection.

8. Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form. Claim 1 is already limited to a parasite which has a reduced ability to infect or survive within macrophages because of its transfection with GM-CSF, so claim 4 does not appear to be further limiting.

9. No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

June 2, 2003

Gary L. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
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